

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 09600-00031-US U.S. APPLICATION NO. (U.S. Patent No. 37 CFR 1.51) 10/538223
INTERNATIONAL APPLICATION NO. PCT/EP2003/012675	INTERNATIONAL FILING DATE 13 November 2003	PRIORITY DATE CLAIMED 9 December 2002
TITLE OF INVENTION FORMULATION WHICH CAN BE ADMINISTERED GASTROINTESTINALLY, AND THE USE THEREOF		
APPLICANT(S) FOR DO/EO/US Heinz Schneider		

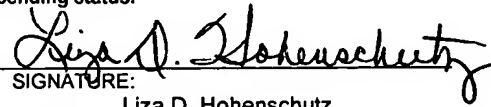
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Form PCT/RO/101, Form PCT/IB/308, Postcard, Certificate of Express Mail

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. 10/538222		INTERNATIONAL APPLICATION NO. PCT/EP2003/012675		ATTORNEY'S DOCKET NUMBER 09600-00031-US	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21.	<input checked="" type="checkbox"/> Basic national fee	\$300	\$	300.00	
22.	<input checked="" type="checkbox"/> Examination fee				
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)					
All other situations					
23.	<input checked="" type="checkbox"/> Search fee				
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority					
International Search Report prepared and provided to the Office					
All other situations					
TOTAL OF 21, 22 and 23 =				\$	900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
16 - 100 =	/50 =		x \$250.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	17 - 20 =	0	x	\$	0.00
Independent claims	2 - 3 =	0	x	\$	0.00
MULTIPLE DEPENDENT CLAIM(s) (if applicable)			+	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	900.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	
SUBTOTAL =				\$	900.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				+	\$
TOTAL NATIONAL FEE =				\$	900.00
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$	900.00
				Amount to be refunded:	\$
				Amount to be charged:	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>03-2775</u> in the amount of \$ <u>900.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>03-2775</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <div style="text-align: right;">  SIGNATURE: Liza D. Hohenschutz NAME </div> <p>CUSTOMER NUMBER: 23416</p> <div style="text-align: right;"> 33,712 REGISTRATION NUMBER <u>June 9, 2005</u> </div>					

10/538223

JC17 Rec'd PCT/PTO 09 JUN 2005

Application No. (if known): Not Yet Assigned

Attorney Docket No.: 09600-00031-US

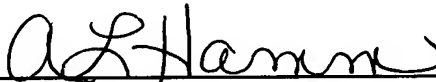
Title: Formulation Which Can Be Administered Gastrointestinally, and the Use Thereof

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV622756708US in an envelope addressed to:

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on June 9, 2005
Date



Signature

Amy L. Hamm

Typed or printed name of person signing Certificate

Registration Number, if applicable

(302) 658-9141

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Letter to the United States Designated-Elected Office
Fee Transmittal
Application Data Sheet
Copy of International application PCT/EP2003/012675 with search report attached
Form PCT/RO/101
Form PCT/IB/308
English language translation of International application
PCT/EP2003/012675
Information Disclosure Statement, PTO SB08, with references
Preliminary Amendment
Postcard
Charge \$900.00 to deposit account 03-2775